NDA 21-007/S-009/S-009
NDA 21-039/S-008/S-008

GlaxoSmithKline
Attention: Robert Watson
Director, Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Watson:

Please refer to your supplemental new drug applications dated January 29, 2001, received January 30, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AGENERASE® (amprenavir) Capsules and Oral Solution.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for changes in the following sections:

- The statement "**ALERT: Find out about medicines that should not be taken with AGENERASE"** was added to the WARNINGS, PRECAUTIONS, patient package insert and container labeling.

- A new section was added to the patient package insert entitled "**MEDICINES YOU SHOULD NOT TAKE WITH AGENERASE"**, and included a listing of drugs that are contraindicated for co-administration with Agenerase.

- A new section was added to the patient package insert entitled "**Medicines That Require Dose Adjustments of Special Attention From Your Doctor"**.

- References to pravastatin from the PRECAUTIONS section were removed.

- The statement, "**ALERT: Find out about medicines that should not be taken with AGENERASE"** is in red font inside a red ALERT box on the container labeling. This is followed by the statement, "Note to Pharmacist: Do not cover ALERT box with pharmacy label."

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted January 29, 2001, patient package insert submitted January 29, 2001, immediate container and carton labels submitted January 29, 2001).

Accordingly, these supplemental applications are approved effective on the date of this letter.
If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Leslie Stephens, MSN, RN, Regulatory Project Manager, at 301-827-2335.

Sincerely,

Debra Birnkrant, M.D.
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research